Case No. 22-16770

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

NATURAL GROCERS, CITIZENS FOR GMO LABELING, LABEL GMOS, RURAL VERMONT, GOOD EARTH NATURAL FOODS, PUGET CONSUMERS CO-OP, NATIONAL ORGANIC COALITION, AND CENTER FOR FOOD SAFETY

Plaintiffs-Appellants,

v.

THOMAS J. VILSACK, *et al*.,

Defendants-Appellees,

APPEAL FROM THE UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF CALIFORNIA

Case No. 20-5151 (Hon. Judge James Donato)

AMICI CURIAE BRIEF OF THE NON-GMO PROJECT AND THE HEALTH RESEARCH INSTITUTE IN SUPPORT OF APPELLANTS' BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel of record for *amici curiae* certifies that the Non-GMO Project and the Health Research Institute, two 501(c)(3) non-profit organizations, as of this date, do not have any parent corporations and no publicly held corporation holds 10% or more of their stock.

RULE 29(A)(4)(E) CERTIFICATION

I, Jessica L. Blome, undersigned counsel for the Non-GMO Project and the Health Research Institute, certify that a party's counsel did not author this brief in whole or in part; neither a party nor a party's counsel contributed money that was intended to fund preparing or submitting this amicus curiae brief; and no person, other than the *amici curiae*, its members, or its counsels, contributed money that was intended to fund preparing or submitting the brief.

Dated: September 12, 2023

/s/ Jessica L. Blome
Jessica L. Blome

THE NON-GMO PROJECT AND HEALTH RESEARCH INSTITUTE'S AMICI CURIAE BRIEF IN SUPPORT OF APPELLANTS' BRIEF

The Non-GMO Project and Health Research Institute respectfully file the accompanying *amici curiae* brief in support of Appellants' Brief. The United States Department of Agriculture's National Bioengineered Food Disclosure Standard, 7 CFR § 66.1-66.406, which implements the National Bioengineered Food Disclosure Act, creates a chasm between federal regulation and long-established food labeling standards in the United States, which only contributes to consumer confusing, rather than alleviating it as Congress intended. *Amici curiae* respectfully request that the Court reverse and remand this case to the District Court with instructions to vacate the USDA's Food Disclosure Standard and develop new rules that comply with the National Bioengineered Food Disclosure Act's requirements for consumer disclosure.

Per Local Rule 29-3, all parties consented to the filing of this brief.

I. Amicus Curiae's Statement of Interest

The Non-GMO Project is a mission-driven nonprofit organization offering rigorous product verification and trustworthy education that empowers people to care for themselves, the planet, and future generations. It was founded on a deeply held belief that everyone has a right to know what is in their food and that everyone should have access to non-GMO choices. In support of its mission, the Non-GMO Project offers a Product Verification Program (PVP) that allows

participants to enroll wholesale goods and retail consumer goods as products for evaluation against, and determination of compliance with, the Non-GMO Project Standard. The first products bearing the Non-GMO Project certification mark hit shelves in 2010. Today, the Non-GMO Project verification is one of the fastest-growing labels in the retail sector and is now featured on over 64,000 products representing almost $44 Billion in annual sales.

The Non-GMO Project's process and testing-based program ensures that all Non-GMO Project verified products are compliant with our rigorous and thorough standard, and that they are clearly labeled so that consumers can make informed decisions if they choose to avoid GMOs. Through this work, the Non-GMO Project has developed a deep understanding of both brand and consumer expectations regarding GMO transparency, which is informed not only by its technically in-depth work with industry supply chains, but also by its robust communications with the more than 1.2 million followers of their social media accounts.

The Health Research Institute employs cutting-edge mass spectrometric and molecular genetic approaches to make the invisible visible. The new scientific knowledge it generates catalyzes transformation in both the biomedical and the nutritional-food-agricultural sectors. Dr. John Fagan is Chairman and Chief Scientific officer of the Health Research Institute and the Global ID Group, an

international company that verifies food purity, quality, and sustainability, and is principal investigator for several bio-safety research projects. He has conducted biomedical research at the U.S. National Institutes of Health, examining molecular mechanisms in carcinogenesis. His research has been published in leading scientific journals and has been supported by millions of dollars in grant awards, including the prestigious National Institutes of Health Research Career Development Award. He holds a Ph.D. in molecular biology, biochemistry, and cell biology from Cornell University.

The Health Research Institute and Chairman Fagan pioneered the development of innovative tools to verify food purity and sustainability, including testing methods to detect genetically engineered organisms in the food supply, the first certification program for non-genetically engineered foods, and a leading program for certifying corporate sustainability and ethics in the food and agricultural industries (ProTerra Certification).

This *amici* brief will help inform this Court's consideration of the National Bioengineered Food Disclosure Act and the USDA's implementing regulations. The Non-GMO Project joins the Health Research Institute and files this brief to provide the Court with their considered perspective on the labeling of GMO products and the technical feasibility of requiring labeling for what the USDA calls "highly-refined foods."

II. Background

The National Bioengineered Food Disclosure Act (Pub. L. 114-216) directed the Secretary of Agriculture to establish a national labeling standard for all foods that are genetically engineered or contain genetically engineered ingredients. The Secretary delegated authority for establishing and administering the standard to the Agricultural Marketing Service (AMS) of the USDA. But the USDA's Food Disclosure Standard confusingly prohibits the use of widely recognized acronyms and terms, such as GE (genetically engineered) and GMO (genetically modified organism), instead allowing only for the labels disclosing that a food is "bioengineered" or "BE." The USDA's decision to prohibit known terms in favor of a brand new, unnecessarily scientific label deliberately obfuscates the presence of non-GMO ingredients in contravention of Congress's policy of disclosure. Further, USDA's Food Disclosure Standard indefensibly exempts "highly refined" foods with "undetectable" bioengineered material from disclosure, excepting most processed foods from the USDA's Food Disclosure Standard altogether.

III. Argument

A. American consumers expect foods containing GMO ingredients to be disclosed on food labels.

The Non-GMO Project provides a voluntary certification scheme that offers North America's most rigorous and recognized program for GMO avoidance through its Product Verification Program (PVP). The Project's PVP is based on a

practice-oriented and process-oriented Standard that uses testing, affidavits, and auditing as key strategic tools to confirm that practices and processes meet expectations. Continuous improvement on the part of PVP participants is required with the common goal of eliminating any inputs or ingredients derived from GMOs from their supply chains. As such, there are no blanket exceptions for "highly refined" ingredients made from GMOs, and most (if not all) inputs and ingredients are required to be sourced from non-GMO sources.[1]

The Non-GMO Project has advocated for years that highly refined food products (such as oils and sugars) derived from genetically engineered ingredients should require disclosure. Just because a food or food ingredient may not contain detectable levels of genetic material from a "bioengineered" source does not mean that the food or ingredient does not contain any genetic material; it only means that it is not detectable using present-day, readily available scientific methods.

The Non-GMO Project is the industry leader in non-GMO labeling in North America. There are no blanket exceptions in the Non-GMO Project's Standards for "highly refined" ingredients made from GMOs, and American consumers expect foods containing such ingredients to be labeled. In fact, extensive consumer research has shown that more than 90% of Americans support mandatory labeling

[1] The Non-GMO Project, Non-GMO Project Standard 03.31.2023 (2023), https://nongmo.wpenginepowered.com/wp-content/uploads/Non-GMO-Project-Standard-Version-16.1.pdf.

on foods that have been genetically modified or contain genetically modified ingredients.[2] In its thirteen years of working with consumers, the Non-GMO Project consistently hears feedback that consumers also want to know whether their food has been processed using any form of genetic engineering (GE) at any stage in the production process—from seed, to animal feed, through the processing of all ingredients in the final product. For a growing number of consumers, GMO transparency through the entire production chain, as well as the final product, matters. The Non-GMO Project Standard has responded to public feedback to provide assurances to consumers who want to know whether the product has been processed using any genetic engineering at any stage in the production. In sum, the

[2]Annenberg Public Policy Center, Americans Support GMO Food Labels But Don't Know Much About Safety of GM Foods (July 18, 2016), https://www.annenbergpublicpolicycenter.org/americans-support-gmo-food-labels-but-dont-know-much-about-safety-of-genetically-modified-foods/ (88% of respondents supported labeling of GM foods); Tracy Loew, *Most voters want GMO food labels, poll finds*, Statesman Journal (December 1, 2015), https://www.statesmanjournal.com/story/tech/science/environment/2015/12/02/most-voters-want-gmo-food-labels-poll-finds/76628010/ (89% of respondents supported labeling of foods containing genetically engineering ingredients); Consumer Reports National Research Center, Consumer Support for Standardization and Labeling of Genetically Engineered Food 2014 Nationally-Representative Phone Survey (2014), https://justlabelit.wpenginepowered.com/wp-content/uploads/2015/02/2014_GMO_survey_report.pdf (92% of consumers stated genetically engineered foods should be labeled); Allison Kopicki, *Strong Support for Labeling Modified Foods*, The New York Times (July 27 2013), https://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html (93% of respondents reported that foods containing genetically modified or engineered ingredients should be labeled); Consumer Reports National Research Center, Food-Labeling Poll 2008 (November 11, 2008), http://justlabelit.wpenginepowered.com/wp-content/uploads/2015/02/foodpoll2008.pdf (95% of consumers stated GMO foods should be labeled).

entire supply and production chain, as well as the final product, matters to American consumers.

Prominent food manufacturers, observantly, have also taken note of consumers' demands to know how their food is grown and made. In January 2016, Campbell Soup Company became the first major United States food company to support national mandatory GMO labeling on food products.[3] Campbells Soup also committed to print clear and simple language about GMO content on the labels of its United States products, including products that contained highly refined ingredients from oils or sugars derived from genetically modified crops.[4] In 2017, along with myriad of other prominent food manufacturers in the United States, Campbell Soup Company urged the USDA's Agricultural Marketing Service, through the public comment process, to require disclosure for food products even when they contain highly refined ingredients in order to address the established consumer interest in knowing about **all** ingredients derived from genetically engineered crops, regardless of whether the genetic material that would allow for

[3] Comments from Campbell Soup Company Re: National Bioengineered Food Disclosure Standard – USDA AMS Proposed Rule Questions Under Consideration (August 25, 2017), https://www.ams.usda.gov/sites/default/files/media/CampbellSoupCompanyBE.pdf.

[4] *Id.*

the identification of genetic engineering had been processed out or to the point where it is no longer identifiable.[5]

Notably, some of the world's best-known food companies, including Danone North America; Mars, Incorporated; Nestlé USA; and Unilever United States came together to form the Sustainable Food Policy Alliance (SFPA) and submit similar comments to AMS supporting the inclusion of highly refined ingredients and foods, such as oils and sugars derived from genetically engineered crops, within the mandatory disclosure standard.[6] The SFPA noted, in part, that their support for mandatory highly refined ingredient disclosure was grounded in their commitment to transparency.[7] They recognized that consumers are seeking more information about the food and beverage products they consume and use, and that they were committed to providing our consumers with the information they need to make informed choices about these products.[8] To this end, their companies had **already**

[5] *Id.*

[6] Letter from Philippe Caradec, Vice President, Public Affairs and Sustainable Development, Danone North America, PBC, Brad G. Figel, Vice President, Public Affairs North America, Mars, Incorporated, Molly Fogarty, Senior Vice President, Corporate & Government Affairs, United States, Nestle USA, and Tom Langan, North America Director, Sustainable Business & External Affairs, Unilever to United States Department of Agriculture, Agricultural Marketing Service (July 2, 2018), https://www.regulations.gov/document/AMS-TM-17-0050-10964.

[7] *Id.*

[8] *Id.*

been disclosing the use of highly refined ingredients produced from bioengineered crops in our products.[9]

For example, Unilever, one of the world's largest consumer product companies with $70 billion in global sales, specifically referenced in 2017 that inclusion of highly refined ingredients and foods, such as oils and sugars derived from bioengineered crops, within the mandatory disclosure standard was consistent with their position that bioengineering disclosure should be based primarily on traceability of ingredients through the supply chain back to a crop.[10] This philosophy applies to some of the country's most recognizable food and beverage products and brands, including household names such as Ben & Jerry's, Breyers, Klondike, Lipton and Knorr.

The Non-GMO Project similarly advocated that in order to provide meaningful transparency to consumers, AMS must include highly refined foods and animal products produced from animals that consume GMO feed in its disclosure requirements. Simply put, if genetic engineering has been used in the development of a crop or other food input, then the resulting product is a GMO and

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[9] *Id.*

[10] Letter from Patrizia Barone, Ph.D., Regional Regulatory Affairs Vice President, Global Foods & Refreshment and North American Region, Unilever and Samuel Zeller, Ph.D., Head of Regional Regulatory Affairs, Unilever, to United States Department of Agriculture, Agricultural Marketing Service (August 24, 2017), https://www.ams.usda.gov/sites/default/files/media/UnileverBE.pdf.

should be labeled accordingly. While some food manufacturers and organizations may disagree about the utilization of highly refined ingredients derived from GMOs in consumer food products, it's clear that large swaths of the industry **do agree** that their use should be disclosed and transparent.

1. The majority of GMO foods will go unlabeled under the USDA's Food Disclosure Standard, creating a large chasm between the USDA's implementation and well-established food labeling standards in the United States.

Pursuant to the USDA's Food Disclosure Standard, however, only certain foods containing "detectable modified genetic material" must disclose the presence of "bioengineered" ingredients. Therefore, contrary to the overwhelming public and corporate support from across the aisles for mandatory labeling on products that include highly refined ingredients made from GMOs, most processed foods that contain GMO ingredients will likely now go unlabeled. It is estimated that 87% of the food products that contain GMO ingredients do so in the form of "highly refined" GE ingredients, like sugar, corn or their derivatives.[11] Further, products made with new GMO techniques such as CRISPR and TALEN are currently untestable. Without a commercially available test, the modified genetic material is undetectable and thus those foods would not require a BE label.

[11] Colin O'Neil and Sean Perrone-Gray, EWG Analysis: Loophole Could Exempt Over 10,000 GMO Foods From Disclosure Law (June 29, 2018), https://www.ewg.org/news-insights/news/ewg-analysis-loophole-could-exempt-over-10000-gmo-foods-disclosure-law.

In other words, the law does not capture an **overwhelming majority** of the GMO products on the marketplace, is an illusory standard, and effectively exempts all but a small portion of GMO foods from disclosure.

Not only is this revelation extremely disheartening, but it also highlights the schism between the USDA regulations and the already well-established food labeling practices in the United States, including the Non-GMO Project Verified label. Many commenters noted that a determination that highly refined ingredients are considered bioengineered foods would be consistent with reasonable consumer expectations, as established in large part by the Non-GMO Project over the last 13 years.

It is also noteworthy that the United States Department of Agriculture's own National Organic Program, wherein genetic engineering is prohibited, does not contain any similar exceptions for highly refined ingredients. The use of genetic engineering, or GMOs, is prohibited in organic products.[12] This means an organic farmer cannot plant GMO seeds, an organic cow cannot eat GMO alfalfa or corn, and an organic soup producer cannot use any GMO ingredients.[13] To meet the USDA organic regulations, farmers and processors must show they are not using GMOs and that they are protecting their products from contact with prohibited

[12] USDA Organic 101: Can GMOs Be Used in Organic Products? (May 17, 2013), https://www.usda.gov/media/blog/2013/05/17/organic-101-can-gmos-be-used-organic-products.

[13] *Id.*

substances, such as GMOs, from farm to table.[14] In the same way that an average American consumer would expect that products containing "highly refined" GE ingredients are not eligible for the organic label, the Non-GMO Project is confident that American consumers also expect that these products would be subject to disclosure and a bioengineered label pursuant to the new law.

To refuse to implement mandatory disclosure of highly refined ingredients deprives consumers of their right to know what is in their food and to make an informed choice about whether or not to consume genetically modified organisms, concepts that are central to the mission of our organization.[15]

2. Highly-refined foods are also included in international genetically engineered food labeling standards, including the Codex Alimentarius definition of modern biotechnology.

During the multiple public comment periods during which AMS solicited feedback regarding the proposed regulations to implement the National Bioengineered Food Disclosure Standard, the Non-GMO Project argued that to support inclusion of all GMO foods, the law should adopt the definition of Biotechnology (i.e., "Bioengineering") used by Codex Alimentarius (Codex). The Codex definition is the most authoritative international definition, and it is what the

[14] *Id.*

[15] The Non-GMO Project, About the Non-GMO Project (last visited September 11, 2023), https://www.nongmoproject.org/about/.

World Trade Organization looks to in resolving trade disputes. It is also the definition used by the Non-GMO Project, which, as previously established, holds the United States' most well-established industry protocol for GMO avoidance. The Codex definition follows:

> "Modern Biotechnology" means the application of:
>
> > a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or
> >
> > b. fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection.[16]

The inclusion of highly refined GE foods is required to be consistent with international genetically engineered food labeling standards and United States treaty obligations, including the Codex definition of modern biotechnology.

Further, labeling of food products and ingredients produced from genetically engineered crops is mandatory in over 60 countries around the world, including Australia, Saudi Arabia and the countries that make up the European Union.[17] In the European Union, products containing highly refined ingredients, such as oils from genetically engineered canola, corn, and soy, have long required mandatory

[16] Guidelines for the Production, Processing, Marketing and Labelling of Organically Produced Foods 7 (2001), ftp://ftp.fao.org/docrep/fao/005/Y2772E/Y2772e.pdf.

[17] The Non-GMO Project, United States Becomes 65th Country to Label GMOs—But Whose Laws Are the Best? (March 24, 2022), https://www.nongmoproject.org/blog/u-s-becomes-65th-country-to-label-gmos-but-whose-laws-are-the-best/.

disclosure even if there is no detectable genetic material in the end product.[18] During the rulemaking process, many commenters pointed out that disclosing highly refined ingredients would assist international trade, allowing United States exporters to sell products abroad without requiring additional actions to comply with a country's labeling standard for bioengineered food.

The Bioengineered Food Disclosure Act requires that USDA "shall" develop the disclosure standard "in a manner consistent with United States obligations under international agreements." 7 U.S.C. § 1639c(a). Given that the USDA's Food Disclosure Standard exempts most GE products from disclosure, conflicts with the standards of the Codex Alimentarius and is contrary to the established international position, it is wholly unclear how the new law supports this mandate.

B. The only required term(s) pursuant to the statute– "bioengineered" and/or "BE"–are blatantly misleading and virtually unknown to the public.

The Non-GMO Project would be remiss if it neglected to raise, again, our grave misgivings about use of the terms "bioengineered" and/or "BE" as the standardized, baseline language that must be included in all disclosures. While we understand regulated entities are permitted to make other claims regarding

[18] Letter from Philippe Caradec, Vice President, Public Affairs and Sustainable Development, Danone North America, PBC, Brad G. Figel, Vice President, Public Affairs North America, Mars, Incorporated, Molly Fogarty, Senior Vice President, Corporate & Government Affairs, United States, Nestle USA, and Tom Langan, North America Director, Sustainable Business & External Affairs, Unilever to United States Department of Agriculture, Agricultural Marketing Service (July 2, 2018), https://www.regulations.gov/document/AMS-TM-17-0050-10964.

bioengineered foods, it is blatantly inexplicable and misleading that the only required terms were virtually unknown to the public at the time the regulations were published.

In order to firmly establish how egregiously inadequate and misleading the terms "bioengineering" and "BE" are, the Project went as far as submitting a separate terminology report to AMS in 2018 demonstrating in no uncertain terms that "BE food" and "bioengineered food" are terms that were unused and unrecognizable by the public. Meanwhile, it was clear the terms "GMO" and "genetically engineered" are well-established and widely used by the public, as well as various international government bodies and scientific communities around the world. Notably, even as the Project crafts this brief, the terms "bioengineering" and "BE" are **still** absent from the USDA's own Agricultural Biotechnology Glossary, while the more commonly used terms "genetic engineering" and "GMO" are naturally defined.[19]

Furthermore, companies that have led the way with voluntary disclosure of GE ingredients, including Campbell Soup Company and the members of SFPA, have generally used "genetically engineered" or "GMO," pursuant to the various state labeling bills as well as the guidelines in the Whole Foods Market GMO

[19] USDA, Agricultural Biotechnology Glossary, https://www.usda.gov/topics/biotechnology/biotechnology-glossary.

Labeling Policy that was put in place in 2013 with a 2018 deadline.[20] Requiring that these companies amend or change their labels to include terms that have no meaning to the American public is a blatant (and expensive) exercise in obfuscation.

C. The USDA's Standard ignores that GMO DNA detectability testing exists and could be deployed to inform consumers.

According to the USDA, "highly refined foods" will often fall outside of its definition of foods that must be labeled as GMO because they "have undergone processes that removed genetic material such that it cannot be detected using common testing methods." 83 Fed. Reg. at 65,834. This is not true. Indeed, it is not possible to reliably and consistently reduce the levels of genetically modified DNA in genetically modified food materials to the point where common testing methods fail to detect the presence of GMO DNA. The standard PCR methods used by commercial and regulatory laboratories are capable of routinely detecting as little as 0.05% GMO content.[21] When coupled with published methods for isolation of GMO DNA from highly refined substances, these methods are capable of detecting

[20] Whole Foods Market, Whole Foods Market commits to full GMO transparency (March 8, 2013), https://media.wholefoodsmarket.com/whole-foods-market-commits-to-full-gmo-transparency/; Whole Foods Market, GMO Labeling (last visited September 11, 2023), https://www.wholefoodsmarket.com/quality-standards/gmo-labeling.

[21] European Network of GMO Laboratories, Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing (2015), https://gmo-crl.jrc.ec.europa.eu/doc/MPR%20Report%20Application%2020_10_2015.pdf.

GMO DNA in most refined products.[22] Recent development of digital PCR methods increase the sensitivity of methods by at least another one or two orders of magnitude,[23] moreover, and more developments emerge[24] on a regular basis.

The Health Research Institute expects that testing methods and detection technology will continue to evolve with greater and greater sensitivity. Therefore, in the future, there will be an increasingly greater ability to detect the presence of

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[22] A. Iwobi, L. Gerdes, U. Busch, and S. Pecoraro, *Droplet digital PCR for routine analysis of genetically modified foods (GMO) – A comparison with real-time quantitative PCR.* 69 Food Control 205 (2017), https://doi.org/10.1016/j.foodcont.2016.04.048; Lelde Grantiņa-Ieviņa, Lilija Kovaļčuka, Veronika Bargatina, and Irēna Meistere, *Influence of sample homogenization and DNA extraction methods on the quantitative and qualitative parameters of DNA in the detection of GMO impurities*, 19 Environmental and Experimental Biology 59 (2021), https://journal.lu.lv/eeb/article/view/58/51.

[23] A. Iwobi, L. Gerdes, U. Busch, and S. Pecoraro, *Droplet digital PCR for routine analysis of genetically modified foods (GMO) – A comparison with real-time quantitative PCR.* 69 Food Control 205 (2017), https://doi.org/10.1016/j.foodcont.2016.04.048; J. Xu, X. Li, J. Bai, Y. Liu, S. Wang, *et al.*, *Absolute quantitative detection of genetically modified soybean MON87708×MON89788 with stacked traits by digital polymerase chain reaction*, 7 Oil Crop Science 180 (2022), https://doi.org/10.1016/j.ocsci.2022.11.001; D. Morisset, D. Štebih, M. Milavec, K. Gruden, *et al.*, *Quantitative Analysis of Food and Feed Samples with Droplet Digital PCR*, 8 PLOS ONE e72583 (2013), https://doi.org/10.1371/journal.pone.0062583.

[24] F.C.A. Brod, J.P. Van Dijk, M.M. Voorhuijzen, A.Z. Dinon, *et al.*, *A high-throughput method for GMO multi-detection using a microfluidic dynamic array*, 406 Anal Bioanal Chem. 1397 (2014), https://doi:10.1007/s00216-013-7562-1; Y. Du, X. Zhao, B. Zhao, Y. Xu, *et al.*, *A novel emulsion PCR method coupled with fluorescence spectrophotometry for simultaneous qualitative, quantitative and high-throughput detection of multiple DNA targets*, 9 Sci Rep. 184 (2019), 10.1038/s41598-018-36981-1; C. Niu, Y. Xu, C. Zhang, P. Zhu, *et al.*, *Ultrasensitive Single Fluorescence-Labeled Probe-Mediated Single Universal Primer–Multiplex–Droplet Digital Polymerase Chain Reaction for High-Throughput Genetically Modified Organism Screening*, 90 Anal Chem. 5586 (2018), https://doi.org/10.1021/acs.analchem.7b03974; Y. Yu, R. Li, Z. Ma, M. Han, *et al.*, *Development and evaluation of a novel loop mediated isothermal amplification coupled with TaqMan probe assay for detection of genetically modified organism with NOS terminator*, 357 Food Chemistry 129684 (2021), https://doi.org/10.1016/j.foodchem.2021.129684; P. Zhu, C. Wang, K. Huang, Y. Luo, *et al.*, *A Novel Pretreatment-Free Duplex Chamber Digital PCR Detection System for the Absolute Quantitation of GMO Samples*, 17 IJMS 402 (2016), https://doi.org/10.3390/ijms17030402.

GMO DNA in highly refined products that were derived from genetically engineered crops. Thus, linking the regulation disclosure to the concept of detectability of GMO DNA results in two alternatives: (1) if regulated entities are allowed to use the testing method of their choice, the word "undetectable" becomes so easily manipulated that it is meaningless, or (2) if the criterion for "undetectable" is based on the performance of testing technologies, the regulatory system and the food industry will be locked into a perpetual "arms race" scenario, where every development in analytical technology increases the stringency of the specifications that industry is required to meet.

Neither of these alternatives is appropriate. The first ignores Congressional intent to provide consumers with a mechanism for knowing whether the food they are eating has been genetically modified. *See* 7 U.S.C. § 1639, et seq., National Bioengineered Food Disclosure Act. The latter locks the industry into expensive, highly technical testing activities. The simple alternative is to follow the clearly expressed intent of the law and use traceability to verify whether the source of an ingredient is genetically modified or not, or to rely on the "may be" clause contained in 7 U.S.C. § 1639b(a)(1) ("[T[he Secretary shall – establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered."). Instead, the USDA's opts to place a large burden on the industry by obligating companies to

subject foods to ongoing testing activities. The statute's "may be" clause solves this by allowing disclosure whenever GMO ingredients are suspected, as does allowing the use of traceability to establish the origin of an ingredient or product as being derived (or not) from GMOs. The Court should order the USDA to follow the law in its Food Disclosure Standard.

IV. Conclusion

In summary, *amici curiae* respectfully request that the Court reverse and remand this case to the District Court with instructions to vacate the USDA's Food Disclosure Standard, 7 CFR § 66.1-66.406 and develop new rules that comply with the National Bioengineered Food Disclosure Act's requirements for consumer disclosure.

Respectfully submitted this 12th day of September 2023,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32 because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I further certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32 because it contains 4,775 words, excluding exempt material, according to the count of Microsoft Word.

Dated: September 12, 2023,

/s/ Jessica L. Blome
Jessica L. Blome

CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2023, I electronically filed the foregoing brief with the Clerk of Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

Dated: September 12, 2023

/s/ Jessica L. Blome